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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,721	11/10/2003	Michael L. Kahn	WSUR121992	5016

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EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,721	KAHN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-4, 7, 9, and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 3-4, 7, 9, and 13-15 are vague and indefinite because it is unclear how PCR product is transferred into a target sequence by using a site-specific recombination system *in vivo*. It is suggested to amend the claims with active steps.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crouzet et al. (6,143,530, issued November 7, 2000).

Crouzet et al. disclose the site-specific recombination is carried out in vivo (that is to say in the host cell (See column 3, lines 59-61). The genetic construct can also be plasmids, that is to say any linear or circular DNA molecule capable of replicating in a given host cell, containing the gene or genes of interest flanked by the two sequence permitting site-specific recombination (See column 4, lines 9-14). The recombinant DNA is a plasmid comprising an origin of

replication and a marker gene (optionally), two sequences permitting a site-specific recombination placed between the sequences and one or more genes of interest (See column 4, lines 21-31). The specific sequences and the recombinase used belong to the integrase family of bacteriophage lambda (See column 4, lines 38-40). This teaches that the recombination protein comprises lambda integrase. The sequences permitting site-specific recombination are derived from a bacteriophage, such as attP and attB. These sequences are capable of recombining specifically with one another in the presence of a recombinase (See column 5, lines 1-6). The host cell is a bacterium, *E. coli* (See column 9, lines 48-51). The method of Crouzet et al. does not need a prior step of purification of the plasmid (See column 3, lines 34-39).

Crouzet et al. do not explicitly disclose that the first site-specific recombination site is *att*B1, wherein the second site-specific recombination site is an *att*B2 site, wherein the first recombination site partner is an *att*P1 site and wherein the second recombination site partner is an *att*P2. However, these specific recombination sites are not defined with a nucleic acid sequence. Crouzet et al. disclose that the sequences permitting site-specific recombination are derived from a bacteriophage, such as attP and attB (See column 5, lines 1-6) and vector pX2776 possesses the attP and attB, which is generated by PCR amplification (See column 23, lines 43-67). This teaching is inherent that there must be partners for each specific recombination site when the PCR product is transferred into a cell for site-specific recombination. Thus the teachings of Crouzet et al. anticipate the limitations of claims.

5. (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kahn et al. ((US 2003/0219902, issued November 27, 2003).

Kahn et al. disclose a method for cloning a polymerase chain reaction product into a target sequence comprising transferring a PCR product into a target sequence using a site-specific recombination system in vivo (See pg. 3, [0027] and [0078]. The system comprises the integrase/att system from bacteriophage lambda (See pg. 1, [0008]). The target sequence is a plasmid sequence (See pg 2, [0016]) or a genomic sequence (See pg 1, [0009]. The cell is bacterial cell, *E. coli*. (See pg. 2, [0021]. The recombination protein comprises Integration Host factor (See pg. 4, [0040]). Therefore, the teachings of Kahn et al. anticipate the limitations of the claims.

Summary

7. No claims allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung
April 20, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
4/20/06